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D E C I S I O N
of 5 December 2001

Case Number: T 0584/97 - 3.3.2

Application Number: 90300132.9

Publication Number: 0377520

IPC: A61K 31/465

Language of the proceedings: EN

Title of invention:
Use of nicotine for the manufacture of a kit for the treatment of conditions susceptible to said treatment

Applicant/Patentee:
ELAN CORPORATION, Plc

Opponent:
Forschungsgesellschaft Rauchen und Gesundheit mbH

Headword:
Use of nicotine/ELAN CORPORATION

Relevant legal provisions:
EPC Art. 54

Keyword:
"Main and auxiliary requests - novelty: (no) - no new medical indication over the prior art"

Decisions cited:
G 0009/91, G 0010/91, G 0005/83, T 0019/86, T 0051/93, T 0009/81

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0584/97 - 3.3.2

D E C I S I O N
of the Technical Board of Appeal 3.3.2
of 5 December 2001

Appellant: (Proprietor of the patent)
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Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted 27 March 1997 revoking European patent No. 0 377 520 pursuant to Article 102(1) EPC.**

Composition of the Board:

Chairman: P. A. M. Lançon
Members: J. Riolo
S. U. Hoffmann

Summary of Facts and Submissions

I. European patent No. 0 377 520 based on application No. 90 300 132.9 was granted on the basis of 10 claims.

Independent claim 1 as granted read as follows:

1. Use of nicotine for the manufacture of a kit containing separate units of nicotine of varying concentration, such that at least one unit contains a sub-therapeutic dose of nicotine and at least one unit contains a therapeutic dose of nicotine for the treatment of a condition susceptible to nicotine therapy involving the separate or sequential administration of increasing doses of nicotine.

II. Notice of opposition was filed against the granted patent by the opponent (respondent).

The patent was opposed under Article 100(a) EPC for lack of novelty and lack of inventive step and because it was not susceptible of industrial application.

The following document *inter alia* was cited during the proceedings:

(1) DE-A-36 39 418.

III. The decision of the Opposition Division revoked the patent under Article 102(1) EPC. In its view the patent in suit did not meet the requirements of the EPC as far as inventive step was concerned.

As to novelty, the Opposition Division was of the opinion that the subject-matter of the main request of

the contested patent, i.e. the set of claims as granted, differed from the disclosure in document (1) in that the dosages of nicotine in the nicotine units of the kit according to claim 1 varied from sub-therapeutic to therapeutic doses, whereas the preparations according to document (1) contained constant doses of nicotine.

It also concluded that the disclosure in the patent in suit was sufficient for the skilled person to understand and perform the claimed subject-matter and that the requirements for applicability were also fulfilled.

In its opinion, the subject-matter of the contested patent did not however involve an inventive step vis-à-vis the closest state of the art represented by document (1).

It defined the problem to be solved vis-à-vis this document as the provision of a use of nicotine for therapy avoiding side effects.

Having regard, on the one hand, to the teaching in document (1) which envisaged the administration of variable doses of nicotine in time and advocated preparations allowing reduced resorption of nicotine to avoid side effects, and, on the other hand, to the well-known fact that the tolerance to undesired side effects could be built up by nicotine itself, the Opposition Division concluded that the administration of increasing doses, according to the patent in suit, for avoiding initial side effects was merely an obvious alternative among suitable alternatives.

The Opposition Division held that the subject-matter restricted to percutaneous administration of nicotine, as defined in the claims of the auxiliary request filed on 13 February 1997 and as disclosed in claim 7 of the application as originally filed, did not involve an inventive step as this particular type of administration appeared to be known as such in connection with nicotine therapy.

IV. The appellant (patentee) lodged an appeal against the said decision.

V. In its letter dated 2 July 2001, the respondent informed the Board that it did not intend to attend the oral proceedings.

VI. Oral proceedings were held before the Board on 5 December 2001.

VII. The appellant submitted that the claimed subject-matter of the main request was novel as it included novel features. In its view, the novelty of claim 1 could indeed be recognised in the kit containing the varying concentration of nicotine, in the therapy involving the administration of increasing doses of nicotine from sub-therapeutic to therapeutic levels and in the absence of side effects achieved by this therapy.

As to inventive step, the appellant argued that, contrary to the teaching in document (1) that the nicotine dosage could be controlled, the teaching of the patent in suit was that it should be varied from a sub-therapeutic to a therapeutic amount.

In its opinion, neither document (1) nor any other

documents suggested such a measure in order to avoid the side effects of nicotine.

Moreover, it submitted that this measure would not be obvious to the skilled person as it appeared from the expert's declaration filed during the opposition proceedings.

It therefore concluded that the subject-matter of the patent in suit involved an inventive step.

As to the subject-matter of the auxiliary request filed on 13 February 1997, which was restricted to the use of percutaneous formulations, it was of the opinion that it was also inventive as document (1) taught away from this type of administration for nicotine since it recited that the effect of this administration type was very low and did not allow any control.

VIII. The respondent submitted in writing that the disclosure in document (1) that one could take one or (e.g.) two capsules at a time, at intervals, implied to the skilled person that one could also take one capsule first and then two capsules, i.e. increasing amounts of nicotine, as was the case in the contested patent.

Since, in its view, the terms therapeutic and sub-therapeutic amounts were not clear because they depended on the patient to be treated, it concluded that no significant difference could be acknowledged for the claimed subject-matter over document (1). It also raised doubts as to whether the side effects could indeed be avoided by the claimed method.

It further submitted that the claimed use was not

allowable under Article 52(4) EPC as it covered in fact a method of treatment.

The respondent repeated these objections with respect to the subject-matter of the auxiliary request filed on 13 February 1997 and, having regard to the low efficiency of the percutaneous administration of nicotine, it added an objection with respect to Article 83 EPC.

IX. The appellant requested that the decision under appeal be set aside and that the patent be maintained as granted (main request) or with the set of claims submitted with its letter dated 13 February 1997 (auxiliary request).

The respondent had requested in writing that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. *Main request*

2.1 Novelty

As emphasised in decisions G 9/91 and G 10/91 of the Enlarged Board of Appeal (OJ EPO 1993, 408 and OJ 1993, 420, respectively), the purpose of the appeal procedure is mainly to review decisions by departments of the first instance (see G 9/91, point 18). The review of an appealed decision covers necessarily all the grounds considered by the department of the first instance when

taking its decision.

In the present case, the Board notes that lack of inventive step was presented as the ground for opposition in the notice of opposition. However, the issue of lack of novelty was also addressed in the respondent's letters dated 13 February 1996 and 9 December 1996 and comprehensively considered in the appellant's letter dated 13 February 1997 during the opposition procedure. Moreover, the Opposition Division dealt with this issue under point 2.3 of its decision.

Accordingly, the Board is empowered to examine the novelty of the claims under Article 54(2) EPC, which ground falls within the frame of the proceedings.

2.2 Document (1) has been cited under Article 54 EPC as prejudicial to the novelty of the subject-matter of the patent in suit.

Document (1) describes a medicament containing nicotine as the therapeutical active agent. Among the cited medical indications, Morbus Parkinson, Morbus Alzheimer and Colitis ulcerosa are quoted (claim 1; column 2, lines 44 to 57).

It also describes formulations containing various quantities of nicotine (claim 4; column 3, lines 21 to 24 and 28 to 35).

2.3 It must therefore be decided whether claim 1 of the patent in suit contains features which could be regarded as novel vis-à-vis the disclosure in document (1).

In that respect, as emphasised by the appellant, the Board notes that this claim is a "Swiss-type" claim drafted in the form approved by the Enlarged Board of Appeal in G 5/83 (OJ EPO, 1985, 64) to comply with the requirements of Article 52(4) EPC.

Accordingly, in order to compare claim 1 with the disclosure in document (1), it is necessary to construe claim 1 in the light of this decision.

The correct construction of this use claim is the following:

"Use of a substance (nicotine) for the manufacture of a medicament (a kit containing sub-therapeutic and therapeutic units) for therapeutic application (the treatment involving conditions susceptible to nicotine therapy involving the separate or sequential administration of increasing doses of nicotine)".

In fact and in essence, this claim amounts merely to the use of nicotine for treating conditions susceptible to nicotine therapy, independently of its wording which is dictated by the Enlarged Board of Appeal's decision G 5/83.

In other words, what is here factually claimed is the **use of nicotine for the manufacture of a medicament**, without any further specified medical indication. Provided nicotine had never been disclosed before in relation with therapy, such a subject-matter could have been claimed under Article 54(5) as a medicament (First medical indication). This was however here not possible in view of the disclosure in document (1), and it is not the form of the claim chosen by the appellant.

Indeed, the appellant has worded its claim in the form suggested by the Enlarged Board of Appeal when more particularly considering the **so-called second medical indication** (see G 5/83, point 9, OJ EPO 1985, 65), i.e. cases in which the medicament resulting form the claimed use is not in any way different from a known medicament.

In its decision, provided the medicament is for a specified new and inventive application, the Enlarged Board of Appeal admitted that "the required novelty for the medicament which forms the subject-matter of the [second medical use] claim is derived from the new pharmaceutical use" (G 5/83, points 21 to 23).

In the present case, no such new pharmaceutical use over document (1) can be seen.

Even if account was taken of the description or the dependant claims of the patent in suit where specific diseases are mentioned (e.g. Alzheimer disease in claim 6; ulcerative colitis in claim 7), it can be seen that these indications are already disclosed in document (1). Furthermore, although arguing in this direction during the oral proceedings, the appellant did not make any attempt to amend claim 1 accordingly.

2.4 In addition, according to the case law formed by subsequent decisions of the boards of appeal the concept of second medical indication has been extended to cover particular situations, among other cases, the treatment of the same disease with the same compound could also represent a novel therapeutic application when it is carried out on a new group of subjects which is distinguished from the former group (e.g. T 19/86,

OJ EPO 1989, 24).

During the proceedings, the appellant insisted on the absence of side effects achieved by the therapy according to claim 1 of the contested patent, the Board notes that this effect is mainly achieved when the patients to be treated are substantially non-smoking patients for whom the problem linked with the toxicity associated with administering nicotine arises. Claim 1 is, however, not restricted to such a group of subjects. Accordingly, this aspect cannot be taken into consideration for assessing the novelty of claim 1.

2.5 It is true, as noted by the Opposition Division and as emphasised by the appellant, that document (1) does not disclose a kit containing separate units of nicotine of varying concentration. It is however not correct to conclude that the second medical use claim is therefore patentable.

It is indeed clearly established case law that known therapeutic agents might only be protected as a "kit-of-parts" when these components formed a functional unity (i.e. a true combination) through a purpose-directed application (see e.g. T 9/81 OJ EPO 1983, 372, points 5, 6 and 9). In the present case, since the claim as drafted is directed to both non-smokers and heavy smokers, the active ingredients, namely the various doses of nicotine, which are administered in increasing dosage, represent however a mere aggregate of known agents. It would indeed only represent a new combination with the surprising, valuable property that the side-effects to be expected when administring nicotine are absent as far as non-smokers were concerned.

Moreover, it is pointed out that claim 1 of the contested patent is directed neither to a kit containing varying concentration of nicotine *per se*, nor to the use of such a kit, nor to a process for the preparation of such a kit. As discussed under point 2.3 above, the correct construction of this claim remains, in essence, the use of nicotine for treating conditions susceptible to nicotine therapy.

In the said claimed use for the manufacture of the kit, no process step beyond the mere use of nicotine is mentioned and the only effect of this use remains the known therapeutic effect.

2.6 It is also true that document (1) does not disclose the specific regimen of the patent in suit involving the administration of increasing doses of nicotine from sub-therapeutic to therapeutic levels.

As already mentioned above, the aim of the regimen is inter alia the achievement of tolerance in order to alleviate the toxicity associated with administering nicotine to non-smoking patients. Contrary to the unsupported submissions of the appellant during the oral proceedings, it cannot be accepted that this effect is achieved for the whole spectrum of patients, in particular the heavy smokers.

It also appears questionable whether this feature does indeed reflect a medical activity in the industrial and commercial field not excluded from patentability within the terms of Article 52(4) EPC.

This feature of the claim, which relates merely to the prescription of a specific drug regimen for basically

known medical treatments, can not however be considered to represent a further medical indication from which novelty could be derived on the basis of the principles set out in decision G 5/83 (see 2.2).

In view of the above, the Board concludes that the subject-matter of claim 1 does not fulfil the requirements of novelty under Article 54 EPC.

Accordingly, there is no need to consider either the subject-matter of the other claims or the other grounds of opposition.

3. *Auxiliary request*

3.1 Articles 84 and 123 EPC

No objection under Articles 84 and 123 EPC was raised by the respondent with respect to this set of claims and the Board sees no reason to differ.

3.2 Novelty

This set of claims differs from the set of claims of the main request merely because it has been restricted to percutaneous administration of nicotine.

Contrary to the situation in decision T 51/93 of 8 June 1994 (not published in OJ EPO), where it was decided that a different mode of administration for a pharmaceutical can render a second medical use claim novel, the percutaneous administration of nicotine in the present case is already a very well-known mode of administration for nicotine, as acknowledged in the description of the patent in suit itself (column 2,

lines 29 to 33).

Accordingly, this feature cannot restore novelty vis-à-vis document (1) and the considerations and conclusions developed under point 2.1 also hold good for this set of claims.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Townend P. A. M. Lançon